FDA 510(k) Premarket Notification

K110823 PRISMAFLEX

CLEARED

Jun 17, 2011
85 days to decision

K110823 · Product code: **KDI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k110823/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dialyzer, High Permeability With Or Without Sealed Dialysate System (KDI)
Date received	Mar 24, 2011
Decision date	Jun 17, 2011
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gambro Renal Products, Inc.**
Location	Lakewood, CO, US
Contact	KAE MILLER
510(k) history	13 submissions · 13 cleared · 2004-2014